

We invite you to participate in a research study being conducted by investigators from Washington University in St. Louis.

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By verbally agreeing to the information in this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

This is a research study conducted by Dr. Craig Buchman having to do with auditory training for children with hearing impairment. You should carefully consider the information in this consent document and discuss it with the research team. You should understand why you might want to participate, or why you might not want to participate. You may choose to participate or not.

If you agree, you will be volunteering to participate in the research study. As a participant, you will be asked to spend about 30 minutes a day, 7 days a week doing auditory training at home. Training will occur for up to 30 days. Also, you will be asked to complete assessments before starting the training and after completing the 30 days of training. During that time, you will be asked to answer questionnaires and take some speech perception tests. The main risks to you if you participate are potential boredom or fatigue associated with repetitive activities like auditory training.

You may benefit from volunteering because auditory training has, in the past, shown to help speech perception abilities in some people. By volunteering you may help someone else in the future. There is no cost to you and you will be paid up to \$270 (\$10/hr + tablet/speaker valued at \$110) for being a volunteer participant. All of this information will be explained.

You are being asked to participate in this research study because you have a hearing loss and use a hearing aid or cochlear implant and are between the ages of 6 and 12 years of age.

The purpose of this research study is to determine the kinds of speech recognition training that most benefit children with hearing loss through the use of computerized listening games. Research has shown that poor speech recognition leads to poor academic achievement. This project offers a potential solution to this problem.

Drs. Nancy Tye-Murray and Brent Spehar are part of the study team, Washington University employees and founders of a corporation that created the online auditory training system you will use in this study. The name of the company is Customized Learning Exercises for Aural Rehabilitation (cLEAR). Washington University has financial interests potentially related to this study. cLEAR and Washington University can potentially benefit financially from the outcome of this study.

The National Institutes of Health is funding this research study. This means that the Washington University is receiving payments from NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NIH for conducting this study.

If you agree to participate, we would like you to complete a series of assessment tests. Some assessments are questionnaires (via the computer) while others will require a verbal response or require you to touch a computer screen. You can skip any question on the questionnaires that you do not feel comfortable answering. You will be asked to make judgments about what you hear and or see. The examiner will be on a zoom call with you during both the baseline and post assessment. The examiner will record your response on a scoresheet that corresponds with each assessment test. You will be able to ask the examiner any questions you may have during the assessment via the zoom call. The assessment may take up to 1.5 hours to complete and can be completed in 1 to 2 days.

You will then complete 16 hours of online auditory training. You will be provided with a log in that is not your real name to protect your identity. Training is spread over approximately 4 weeks. You will be asked to average about 30 minutes per day of training each week (7 days). We will provide a hand-held tablet for you to use during the training. The training is computerized game-like auditory training. You will listen and make judgments about what you hear. Your responses will be recorded.

At the completion of the training you will be scheduled for another assessment which will include most of the tests/questionnaires you completed before the training along with a satisfaction questionnaire. The assessment may take up to 1.5 hours to complete and can be completed in 1 to 2 days.

As part of this study, we are obtaining data from you. We would like to use this data for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding speech perception in children with hearing loss. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you for use of your data. By allowing us to use your data you give up any property rights you may have in the data.

We will share your data with other researchers. They may be doing research in areas similar

to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or commercial sponsors of research. We may also share your data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

If you change your mind and do not want us to store and use your data for future research, you should contact the research team member identified at the top of this document. The data will no longer be used for research purposes. However, if some research with your data has already been completed, the information from that research may still be used. Also, if the data has been shared with other researchers it might not be possible to withdraw the data to the extent it has been shared.

Identifiers may be removed from your private information and used for future research or shared with others. If this occurs, we will not ask you for additional consent.

Approximately 25 people will take part in this study at Washington University.

You may experience one or more of the risks indicated from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Risks may include boredom or fatigue. Other than that, there are no foreseeable risks and discomforts associated with this research.

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *“How will you keep my information confidential?”* for more information.

You may or may not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because others might benefit in the future in terms of the knowledge that will be gained.

You will not have any costs for being in this research study.

You will be paid \$10 per training hour (\$10/hr for 16 hours = \$160). If you complete the 16 hours of home training and all of the assessments you will be given the tablet and speaker which together is worth approximately \$110. The maximum total cash amount you will receive from completing the study is \$270. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid

if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address if a check will be mailed to you. It will take approximately three weeks to receive your payment via the mail. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

To help protect your confidentiality, we will code all information with a code that will not identify you. A master list linking the code and your identity will be kept separate from the research data. Only the PI and people helping him/her will be able to see the list. We will protect your information.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others;
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

Federal regulatory agencies and Washington University, including the Washington University Institutional Review Board (a committee that reviews and approves research studies) and the Human Research Protection Office may inspect and copy records pertaining to this research. If we write a report about this study we will do so in such a way that you cannot be identified.

As part of this study we will generate Protected Health Information, or PHI. PHI is health information that identifies you and is protected by law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this study you must give the research team permission to use and disclose your PHI as explained earlier in our conversation. The research team will follow state and federal laws and it is possible that other people may become aware of your participation in this study and may inspect records pertaining to the research. This could include university representatives, to complete university responsibilities, and government representatives (including the Office for Human Research

Protections and the Food and Drug Administration), to complete federal or state responsibilities, and NIH.

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about earlier in our conversation. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this letter. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you do not provide authorization for us to use your PHI it will not affect your treatment or the care given by your health provider, insurance payments or enrollment in any health plans, or any benefits to which you are entitled. However, it will not be possible for you to take part in the study. If you agree to take part, you authorize the use of your PHI for this research, and your authorization will not expire. You may later change your mind and not let the research team use or share your information.

In order to revoke your authorization, you will need to complete a withdrawal letter. Please contact the Human Research Protection Office for more information on how to revoke your authorization or contact the research team to request the withdrawal letter. If you revoke your authorization, the research team may only use and share information already collected for the study. Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons. You will not be allowed to continue to participate in the study.

We would like to contact you by email to ask you how training is going and to answer questions that you may have. Some of these emails may contain health information that identifies you.

Only the research team will have access to your email communications. We will only communicate by email to send you the information discussed. If you have any questions or need to contact us for an urgent or emergent situation, please contact the research team.

You should be aware that there are risks associated with sending your health information via email.

- There is always a risk that the message could be intercepted or sent to the wrong email address. To avoid sending messages to the wrong email address, the first email we send you will be a test message to ensure we have the correct email address.

- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any email communications sent or received on any electronic devices used for work or through a work server.

Your participation in this study is completely voluntary. You may choose not to take part at all. If you decide to participate in the study you may stop participating at any time. Any data that was collected as part of this study will remain as part of the study records and cannot be removed. If you decide not to take part in the study or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

If you do not wish to participate in this study or want to end your participation in the study, simply tell me. You will not be penalized or lose any benefits for which you otherwise qualify.

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Elizabeth Mauze at 314-747-7181 or mauzee@wustl.edu. If you feel you have been harmed from being in the study, please contact: Elizabeth Mauze at 314-747-7181 or mauzee@wustl.edu. If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 1-(800)-438-0445 or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, <http://hrpo.wustl.edu>. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

Thank you very much for your consideration of this research study.

**Do you agree to participate?**

\_\_\_\_\_ Yes      \_\_\_\_\_ No

**Do you agree to allow us to send your health information via email?**

\_\_\_\_\_ Yes      \_\_\_\_\_ No